

DATE OUT: 01/JUN/2004

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: Manufacturing-Use [] End-Use Product [X]
DP BARCODE #: D299658 EPA RECEIVED DATE: 13/FEB/2004 FILE SYMBOL/REG : 100-RROO
PRODUCT NAME: Pinoxaden (NOA 407855 100EC Herbicide) ACTION CODE: 165
COMPANY: Syngenta Crop Protection, Inc. FOOD USES [X] MRID: 462030-02 & 462030-04
PPC NUMBER OF THE TGAI IN THE PRODUCT: 147500 DECISION NO.: 340153

FROM: Sami Malak, Chemist *Sami Malak*
Technical Review Branch/RD (7505C)

SRM
6/01/04

TO: 25 James Tompkins/Hope Johnson
Herbicide Branch/RD (7505C)

INTRODUCTION:

In a letter dated 13/FEB/2004, the applicant requested registration of subject end-use product proposing a joint review with the Pest Management Regulatory Agency (PMRA) in Canada. In support of this action, the applicant included product chemistry data, a proposed basic CSF dated 09/JAN/2004, a proposed Label EPA received 13/FEB/2004, Certificate With Respect to Citation of Data, and Data Matrix.

FINDINGS:

1. The subject product was produced by an integrated formulation system, meaning that the active ingredient in the product is undergoing registration. The primary review of the technical source in the product, Pinoxaden, is the purview of PMRA. The product 9.71% Pinoxaden: 2,2-dimethyl-propanoic acid 8-(2,6-diethyl-4-methylphenyl)-1,2,4,5-tetrahydro-7-oxo-7H-pyrazolo[1,2-d[[1,4,5]oxadiazepin-9-yl ester., Reg. No. 100-RRO1.
2. The subject product, a post-emergence herbicide, is intended for grass weed control in wheat, including durum and barley.
3. The submitted product chemistry data is adequate and support registration of subject product.
4. Adequate analytical method is available for enforcement. The method for the pure active ingredient is accomplished by liquid chromatography using method # AF-1518/1. The method is currently under review by PMRA.
5. The label claim nominal concentrations of 9.71% Pinoxaden is consistent with that in the CSF, both are in compliance with the regulations of PR Notice 91-2. Further, the storage and disposal statement and the physical or chemical hazards statement are in compliance with the regulations of 40CFR§156.78.
6. The proposed basic CSF dated 09/JAN/2004, was filled out correctly and completely and agree with the label claim nominal concentration as per the regulations of PR Notice 91-2. Further, the upper and lower certified limits are within the standard limits of 40CFR§158.175(b)(2) & 40CFR§152.43. All ingredients claimed on the CSF are cleared for use in pesticide formulations intended for food uses.

CONCLUSIONS:

Pending registration of the technical source, Pinoxadin, TRB will have no objections for registration of subject product. The proposed basic CSF dated 09/APR/2004 and label EPA received 13/FEB/2004 are acceptable as per Findings 5 & 6 above.

REVIEW OF PRODUCT CHEMISTRY DATA:

1. A statement of data confidentiality dated 09/JAN/2004 was included with this submission claiming confidentiality of some of the submitted data on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C). Review of CBI data has been removed to Confidential Appendix A.
2. A GLP statement dated 09/JAN/2004 was included with this submission to the effect that some of the submitted studies were conducted in compliance with the Swiss Ordinance relating to Good Laboratory Practice, which is based on OECD Principles of GLP requirements.

Group A, Series 830-Product Identity, Composition, and Analysis (40 CFR 155, 160, 162, 167, 175 & 180)**830-1550 Product Identity and Composition**

This product contains one technical grade of an active ingredients currently under review by PMRA, plus cleared inert ingredient intended for food uses (refer to product's basic CSF dated 09/JAN/2004).

830-1600 Description of Materials Used to Produce the Product:
Refer to Confidential appendix A.**830-1650 Description of Formulation Process:**
Refer to Confidential appendix A.**830-1670 Discussion of Formation of Impurities:**
Refer to Confidential appendix A.**830-1700 Preliminary Analysis:**
Refer to Confidential appendix A.**830-1750 Certified Limits:**
Refer to Confidential appendix A.**830-1800 Enforcement Analytical Method:**

Adequate analytical method is available for enforcement. The method for the pure active ingredient is accomplished by liquid chromatography using method # AF-1518/1. The method is currently under review by PMRA.

Identity, Composition, Formulation, and Analysis, Subgroup A, Series 830.1550 to 830.1800
(40 CFR 158.155 to 158.180)

| Guideline Reference NO.(GRN 830.)/Title | Data Fulfilled | MRID No. |
|--|-----------------------|-----------------|
| .1550 Product identity and composition | Y | 462030-02 |
| .1600 Description of materials used to produce the product | Y | 462030-02 |
| .1620 Description of production process | NA | |
| .1650 Description of formulation process | Y | 462030-02 |
| .1670 Discussion of formation of impurities | Y | 462030-02 |
| .1700 Preliminary analysis | NA | |
| .1750 Certified limits | Y | 462030-02 |
| .1800 Enforcement analytical method | Y | 462030-02 |

Explanations: Y = The requirements were fulfilled; N = The requirements not fulfilled; N/A = Not applicable; G = Data gap; U = Requires upgrading; I = Incomplete or in progress; W = Waived.

Physical and Chemical Properties, Subgroup B, Series 830.6302 to -830.7300 (40 CFR 158.190)

The applicant complied with PR Notice 98-1 on self-certification of product chemistry data and submitted an abstract summary of product's physical/chemical properties in EPA Form 8570-36. A self certification statement, EPA Form 8570-37, was included with this submission. The data is summarized in the following table:

| Guideline Reference NO.(GRN 830.)/Title | Data Fulfilled | Value or Qualitative Description | MRID No. |
|---|-----------------------|---|-----------------|
| .6302 Color | Y | Yellow orange. | 462030-04 |
| .6303 Physical state | Y | Liquid. | 462030-04 |
| .6304 Odor | Y | Thymol like | 462030-04 |
| .6314 Oxidation/reduction: Chemical incompatibility | Y | Not an oxidizing substance. | 462030-04 |
| .6315 Flammability/flame extension | Y | > 174°F (79°C) | 462030-04 |
| .6316 Explodability | Y | The product does not contain potentially explosive ingredients. | 462030-04 |
| .6317 Storage stability | Y | Product is known to be stable. | 462030-04 |
| .6319 Miscibility | NA | Is not intended to be mixed with petroleum solvents. | |
| .6320 Corrosion characteristics | Y | Not known to be corrosive to the commercial container. | 462030-04 |
| .6321 Dielectric breakdown voltage | NA | Not recommended for use around electrical equipment. | |
| 7000 pH | Y | 4.71 (1% dispersion in water). | 462030-04 |
| .7100 Viscosity | Y | 8.34 mPas @ 25°C 4.41 mPas @ 40°C | 462030-04 |
| 7300 Density/relative density/bulk density | Y | 8.6 lbs/gal @ 20°C | 462030-04 |
| Explanations: Y =The requirements were fulfilled; N = The requirements not fulfilled; N/A = Not applicable; G = Data gap; U = Requires upgrading; I = Incomplete or in progress; W = Waived. | | | |

Confidential Appendix A

Manufacturing process information may be entitled to confidential treatment